SEP 10 1999

MYOTRONICS-NOROMED, INC.
Leading in Musculoskeletal Evaluation Technologies For Over 25 Years

Attachment 4

K992694

510(k) SUMMARY

~~K-992150~~

1. Submitter's Information

Date of Submission: August 11, 1999
Name and address:

Myotronics-Noromed, Inc.,
15425 - 53 Ave. So., Tukwila, WA 98188
Tel: (206) 243-4214 FAX: (206) 243-3625

Contact Name: Mr. Fray Adib

2. Device Trade Name: Model K6-I Diagnostic System
Common name: Surface EMG System
Classification name: Electromyograph

3. Myotronics-Noromed's intended addition of Fast Fourier Transformation (FFT) of data to the K6-I Software is substantially equivalent to that feature found in:

ProComp DSP & ProComp mfg. by Thought Technology
Myosystem 1000 Electromyograph mfd. by Noraxon
I-330 Physiological Monitor mfd. by J & J Engineering

4. Description of the device:

The Model K6-I Diagnostic System is a surface electromyographic device that measures and records electrical potential emanating from muscle (in addition to its ability to track and document mandibular position/range of motion).

5. The feature being added to the software of this device, Fast Fourier Transformation (FFT) of captured data, has the same technological characteristics as other legally marketed devices described above and in the Special 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 1999

Mr. Fray Adib
President
Myotronics-Noromed, Inc.
15425 53rd Avenue South
Tukwila, Washington 98188

Re: K992694
Trade Name: Model K6-I Diagnostic System
Regulatory Class: II
Product Code: KZM and IKN
Dated: August 11, 1999
Received: August 12, 1999

Dear Mr. Adib:

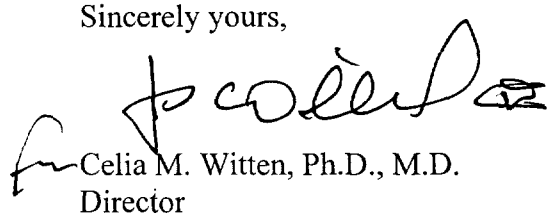
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 992694

Device Name: **Model K6-I Diagnostic System**

Indications for use

For Jaw Tracking functions of this device:

- Tracks mandibular movement and position
- For the diagnosis of functional disorders such as TMJ/MPD syndrome, muscle tension, bruxing, and instability of occlusion
- Identification of mandibular rest position
- Identification of interocclusal distance and freeway space
- Monitors the position of the jaw in three dimensions
- Represents the spatial position of the mandibular incisal edge relative to the skull

For electromyographic function of this device:

- Intended for use for muscles of mastication, especially temporalis, masseter, and digastric
- Designed to perform a limited number of functions in dental diagnosis

(continued on page 2)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992694

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

510(k) Number: K992694

Device Name: Model K6-I Diagnostic System

Indications for use – electromyographic functions of this device **(continued from page 1)**

- For use as a stand alone system for clinical monitoring of up to eight different muscles. it is ideally suited for diagnosis and treatment evaluation by recording function/dysfunction of the muscles of the stomatognathic system
- The determination of the degree of relaxation of a particular muscle or muscle group at rest
- The precise measurement of relative levels of contraction of several muscles during a functional test

For both functions of this device:

- Diagnosis and management of TMJ/MPD disorders, orthodontic patients, denture patients, and reconstruction patients.

The addition of the feature described in this new Premarket Notification does not expand upon the above indicated uses.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992694

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)